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Sinpei Nakata

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SUITE 370

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EXAMINER

ALEXANDER, LYLE

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/936,918
Filing Date: November 01, 2001
Appellant(s): NAKATA ET AL.

Mr. Daniel Stranger
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/23/08 appealing from the Office action mailed 8/24/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

NEW GROUND(S) OF REJECTION

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 6 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fritchie et al.(USP 6,022,746).

Fritchie et al. teach a method of allocating resources of an automated analyzer to optimize analysis. Column 5 line 1 through column 7 line 37 teaches system(10) software that tracks the reagent inventory and notifies the user when needed. The device also tracks the calibration status of test and lot numbers for each of the instruments(12A-12D). Fritchie teach in column 6 lines 6-16 a system(10) that contains all of the necessary software connected to plural instruments 12A, 12B, 12C, and 12D. The system(10) has been read on the claimed "service center." In column 6 lines 17-24, Fritchie teaches a data management portion which generates outputs that control the various operations of the automated analyzer. The instant language is sufficiently broad to have been properly read on the taught data management portion. Fritchie teach in column 5 lines 55-63 identification of the current reagent inventory and comparison with a theoretical reagent map. These steps clearly meet the claimed limitations of storing data base parameters relating to the reagents. Fritchie teach in column 6 lines 6-16 a system(10) that contains all of the necessary software connected to plural instruments 12A, 12B, 12C, and 12D.

Fritchie et al. is silent to the claimed steps of calculating a statistical standard value.

Carbonari et al. teach a random access analyzer for automatically conducting colorimetry, photometric and other tests on biological fluids that are routinely required in a clinical environment. The analyzer automatically tracks the sample and reagents necessary to perform the tests. Column 4 lines 10-18 teach "A built in quality control system monitors the tests for statistical deviations. All of these and other functions and parameters are within the skill of those of ordinary skill in the art to implement." It is known and desirable to monitor the statistical deviation of the data to determine the certainty and confidence of the results. The Office has read this on the claimed "... calculating, ... a statistical standard value ... calculating ... a statistical deviation ... determining, based on the calculated statistical deviation, whether the analysis parameter used in the analysis are correct."

It would have been within the skill of the art to modify Fritchie et al. in view of Carbonari et al. and include a quality control system that tests for statistical deviations to determine the certainty and confidence of the results.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,022,746	FRITCHIE	2-2000
5,730,938	Carbonari et al.	03-1998

(9) Grounds of Rejection

See the above new grounds of rejection.

(10) Response to Argument

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(a) With respect to claim 1, Appellants state Fritchie does not teach a “service center” that calculates and disseminates results to plural facilities. Appellants’ further state Fritchie fails to include calculating a “statistical standard value” and “statistical deviations” to determine if the analysis parameters used are correct.

Fritchie teach in column 6 lines 6-16 a system(10) that contains all of the necessary software connected to plural instruments 12A, 12B, 12C, and 12D. The system(10) has been read on the claimed “service center.” Carbonari et al. teach a quality control system that monitors the test results for statistical deviations which has been read on the claimed calculations of “statistical standard values” and “statistical deviations.” The Office has combined Fritchie in view of Carbonari et al. and believes all of the claimed limitations have been met.

(b) With respect to claim 2, Appellants state the rejections of record have not addressed the claimed “transferred analysis parameters.” Fritchie teaches in column 6 lines 17-24 a data management portion which generates outputs that control the various operations of the automated analyzer. The instant language is sufficiently broad to have been properly read on the taught data management portion.

(c) With respect to claim 3, Appellants state Fritchie fails to teach storing database parameters related to the reagents. Fritchie teach in column 5 lines 55-63 identification of the current reagent inventory and comparison with a theoretical reagent map. These steps clearly meet the claimed limitations of storing data base parameters relating the reagents.

(d) With respect to claim 6, Appellants state Fritchie fails to teach the claimed method of registering a new reagent in the analyzer. Fritchie teaches in column 5 lines 55-63 identifying the reagent packs loaded into the analyzer which has been read on the limitations of claim 6.

(e) With respect to claim 8, Appellants states Fritchie do not teach calculation of the statistical deviations from the standard value. In light of the new grounds of rejection above, Fritchie in view of Carbonari et al. teach a quality control system that calculates statistical deviations and has been properly read on claim 8.

(f) With respect to claim 9, Appellants state Fritchie does not teach the claimed analysis of a control sample from one of the apparatuses and the subsequent standard deviation calculation. Fritchie in column 5 lines 55-63 additional calibrations are made on the instruments 12A, 12B, 12C, 12D. Fritchie in view of Carbonari et al. teach a quality control system that calculates statistical deviations of the controls and has been properly read on claim 9.

(g) With respect to claim 10, Appellants state Fritchie fails to teach the claimed step of recognizing when no defect is present, the data is stored as valid. In light of the new grounds of rejection above, Fritchie in view of Carbonari et al. teaches calculation of the statistical deviation and would save the valid data.

(h) With respect to claim 11, Appellants state Fritchie fails to periodically calculate the standard value. In light of the new grounds of rejection above, Fritchie in view of Carbonari et al. teach a quality control system that calculates statistical deviations and has been properly read on claim 11.

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(i) With respect to claim 12, Appellants state Fritchie fails to teach a service center that stores and manages programs for the automated analysis instruments. Fritchie teach in column 6 lines 6-16 a system(10) that contains all of the necessary software connected to plural instruments 12A, 12B, 12C, 12D and has been properly read on claim 12.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section (6) above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be

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treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

/Lyle A Alexander/
Primary Examiner, Art Unit 1797

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/Gregory L Mills/
Supervisory Patent Examiner, Art Unit 1700

Conferees:

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797*

/Gregory L Mills/
Supervisory Patent Examiner, Art Unit 1700